EXHIBIT A

Not Reported in F.Supp., 1990 WL 121353 (E.D.Pa.), 18 U.S.P.Q.2d 1977
(Cite as: Not Reported in F.Supp.)

United States District Court, E.D. Pennsylvania.

ORTHO PHARMACEUTICAL CORPORATION, Plaintiff,
v.
Herchel SMITH, American Home Products Corporation, and Wyeth-Ayerst Laboratories, Defendants.
AMERICAN HOME PRODUCTS CORPORATION, Counterclaim Plaintiff,
v.
JOHNSON & JOHNSON, Counterclaim Defendant.

CIV. A. No. 90-0242.

Aug. 17, 1990.

Albert G. Bixler, Daniel Segal, Hangley, Connolly, Epstein Chico, Foxman & Ewing, Philadelphia, Pa., Stephen B. Judlowe, Marguerite Del Valle, Joseph Mazzarese, Hopgood, Calimafde, Kalil Blaustein & Judlowe, New York City, pro hac vice, Dennis J. Mondolino, for plaintiff.
Steven R. Petersen, Michael T. Scott, Reed, Smith, Shaw & McClay, Philadelphia, Pa., Paul H. Heller, Kenyon & Kenyon, New York City, pro hac vice, for American Home Products Corporation.*TABLE OF CONTENTS*

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FINDINGS OF FACT AND CONCLUSIONS OF LAW

NEWCOMER, Senior District Judge.

FINDINGS OF FACT.

I. *The Non-Obviousness of Claims 5, 19, 40, and 43 of the '322 Patent.*

*1 A. *Ortho's In-House and Outside Counsel Did Not Find Claims 5, 19, 40 and 43 of the '322 Patent Obvious.*

1. During his deposition, shortly before trial, Mr. Lambert, J. & J's in-house patent counsel testifying as a Rule 30(b)(6) witness on the subject of Ortho's defenses and contentions, admitted that Ortho knew of no prior art which taught or suggested claims 5, 19, 40, or 43 of the '322 patent.

Q. Is there any combination of publications which you say suggest the subject matter of Claim 5?

A. You have already asked me if any of them suggest Claim 5. If none of them suggest Claim 5, how can they in combination suggest Claim 5?

Q. That is my understanding also, but I have to cover it. Does any combination of the publications suggest the subject matter of Claim 19?

A. No.

...

Q. What combination of publications or patents suggests the subject matter of Claims 40 or 43?

A. Let me rephrase the answer. I believe that the prior art is relevant to those claims. I can't say they suggest the specific subject matter, but they are certainly relevant to the subject matter. (Dep. Lambert 28, 58-60).

Mr. Lambert has been involved with patent questions on norgestimate since 1973. (Dep. Lambert 4/7/90 70).

2. Dressler, Goldsmith, Clement, Gordon & Shore, Ltd., the firm of Dr. Gamson (a patent expert for Ortho at trial), gave J & J a series of opinions on the subject of validity from 1976 to 1990. (Exhs. D-202, D-203, D-204, D-344). Its first opinion on the validity of the '322 patent was issued in 1977. Dr. Gamson's firm stated:

Our conclusion of validity with respect to claims 7, 19, 28, 35, and 36 of U.S. Patent 3,959,322 is not restricted to validity with respect to the aforementioned Belgian patents. We believe that the subject matter of these claims is also patentable over any prior art we know of including the Bachmann et al. and Marker articles called to the attention of the Examiner by the attorneys for Hughes et al., as discussed above. (Exh. P-203, at

31).

Narrow claims 7, 19, 28, 35 and 36 of U.S. Patent 3,959,'322 are specific to Norgestrel and to a limited class of compounds including Norgestrel. These narrow claims are valid over any prior art known to us (Exh. P-203, at 3).

3. The author of the opinion was aware of the prior art norethindrone as well as the Fieser and Fieser reference. (Exh. P-203 at 21-22). No different opinion on this issue of validity was prepared subsequently although the issue of defenses to the '322 patent was raised in another opinion in 1990. (Tr. Gamson 433, Exh. P-344).

B. *The Scope and Content of the Prior Art of Steroid Hormones.*

1. *Steroids*

4. Steroids comprise a class of chemical compounds which has a distinctive four ring structure of three hexagonal rings of carbon atoms (the " six-membered rings") and one pentagonal ring (the " five member ring") all fused together in a substantially linear shape. The three hexagonal rings are lettered A, B and C; the five membered ring is D. The 17 carbon atoms which make up the four rings are numbered 1-17; a single carbon atom with 3 attached hydrogen atoms (a "methyl group") at position C-13 is numbered 18. The steroid molecule is basically a flat plane. The top side (above the plane) is called the "B" face; the bottom side (below the plane) is called the "a" face. (Exhs. P-105; D-314). All the claims of the '322 patent are directed to "13-ethyl gon-4-enes," that is, steroids with a gonane skeleton having an ethyl group at the 13 position, and a double bond at the 4 position. The claims at issue in this litigation all also have a 17B-hydroxy or 17B-acetate, and a 17a-ethynyl group. The claims in issue are 5, 19, 40 and 43. (Exh. P-105, P-111; D-314, D-334).

*2 5. Steroids can be made or "synthesized" by two principal methods: total synthesis, starting from scratch, from commercially available chemicals, and partial synthesis, or synthesis from pre-formed steroids or steroid pieces. Total synthesis is a very involved procedure. The steroid molecule must be carefully built-up piece by piece, through a dozen or more steps from which each desired material must be separated and identified. (Tr. Hughes 538-39, 542 Exh. D-338).

2. *Steroid Sex Hormones*

6. Hormones are chemicals found in the body which are produced in one part of the body, and deliver a message to another part of the body. Hormones deliver their message by binding to a cellular receptor (the "receptor site") whereupon the complex of hormone bound to the receptor causes further physiological changes to occur. The binding of a hormone to a receptor can be likened to a key fitting into a lock. Just as a key must have precisely the right shape to fit into a particular lock, so a hormone must have the proper shape to fit into a receptor. (Tr. Torig 590-91).

7. There are three classes of sex hormones. All have similar structures, including a methyl group at C-13. Nevertheless, the three steroids, progesterone, testosterone and estradiol, all have vastly different biological properties, and each binds only to its own receptor. Progesterone and estradiol are female sex hormones, regulating the female reproductive cycle, while testosterone is the male sex hormone, which also has anabolic (i.e., muscle-building) characteristics. The small structural differences between these hormones can be contrasted to their enormous biological differences: the difference between boys and girls. (Tr. Rorig 590-91).

3. *The Prior Art Asserted by Plaintiff Ortho*

8. Ortho asserted that the '322 patent was obvious in view of two prior art references: *Steroids* by Fieser and Fieser, a 1959 treatise on the chemistry and properties of steroids (Exh. P-98), which discloses the compound norethindrone, having a methyl group at the 13-position, and Belgian patents 595,384 through 595,388 (Exhs. P-80-P-84), by Smith and Hughes, which disclosed certain C-13 polycarbon steroids, specifically "(±) 8,14-dehydro-18-homo-estrone methyl ether". (or, more simply, the "Belgian intermediate"). (Exh.

P-117; Tr. Doorenbos 171-72, 182-83). The *Steroids* treatise was cited by the Patent Office Examiner as a reference during the proceedings for the '911 patent. (Tr. Doorenbos 234-35).

9. Norethindrone was known to be a progestin. However, there was no known way of transforming norethindrone into norgestrel (i.e., adding a carbon atom to the C-13 methyl group of norethindrone). (Tr. Hughes 553, Rorig 605, Doorenbos 242-43). During the proceedings for the '322 patent, the Patent Office concluded that norgestrel and related compounds were patentable over norethindrone. (Tr. Bjorge 919, Exhibit P-57, ¶ 8).

10. The Belgian patent does not disclose any 13-ethyl gon-4-enes. There are at least six major structural differences between the Belgian product and norgestrel. (Tr. Doorenbos 265-70; Rorig 623-624) And, in the 1950s and early 1960s, there was no known way of transforming the Belgian intermediate into norgestrel. Furthermore, nothing was said about the biological properties of the Belgian intermediate in the Belgian patent. (Tr. Rorig 624). For example, comparing the structures of claim 5 and the Belgian patent:

Position	'322 Patent Claim 5	Belgian Pat. 595,385
3	ketone	methoxy
8	saturated	unsaturated
14	saturated	unsaturated
17	ethynyl and hydroxy	ketone
A ring	single unsaturation at the 4 position	triple unsaturation

(Tr. Rorig 623-624).

*3 4. *Prior Art Synthesis of 13-Ethyl Gon-4-enes*

11. The court finds that prior to the invention of Smith and Hughes no one had made any 13-ethyl gon-4-enes (Tr. Rorig 594-595). Since all the natural steroids are 13-methyl steroids, synthesis of a 13-ethyl gon-4-ene required a total synthesis. (Tr. Rorig 593-594, 603-606).

5. *Structure-Activity Relationships in the Steroid Sex Hormones*

12. There are two types of drug activity: structurally specific and structurally non-specific. With drugs which exhibit structurally non-specific activity, binding to a cellular receptor is not important, and was not believed to be important in 1960. As Professor Doorenbos explained in 1960 (Exh. P-99),

structurally specific activity is dependent upon factors such as the presence or absence of certain groups, intramolecular distances, and the shape of the molecule. Activity is not easily correlated with any physical property, and small changes in structure often lead to great changes in activity. Structurally specific activity appears to be dependent upon the interaction of the drug with a cellular receptor. (emphasis added).

Steroid hormones exhibit structurally specific activity. (Tr. Rorig 609-10). The structural specificity of steroid hormones meant that in the 1950s and early 1960s one could not predict the effect of small structural changes on the biological activity of steroid hormones. (Tr. Rorig 610).

13. Dr. Howard J. Ringold, the director of chemical research for Syntex laboratories, one of the leading pharmaceutical houses involved in progestin and oral contraceptive research during the 1950s and early 1960s, and which invented norethindrone (Exh. P-98 at 591), gave a presentation at a conference on steroid hormones, which was published in 1961. In his paper, Dr. Ringold summarized the state of the art of correlating the structure of steroids with their activity as follows:

During the past ten years, many hundreds of new steroids have been synthesized. Many of these are analogues of naturally occurring hormones. Some of these compounds have surpassed their basic prototype in biological activity, some have been less active, while many have exhibited types of normal activity completely unexpected on the basis of compound structure. The desire of the steroid chemist to tailor design and synthesize compounds to meet specific biological or clinical needs however is still far short of realization. Most, if not all, of the major discoveries in the steroid field leading to the substances with clinically more desirable biological properties have been accidental. (Tr. Rorig 614).

The court finds this contemporaneous characterization of steroid discoveries as being " accidental" more credible than hindsight assertions of predictability made more than thirty years afterwards.

14. Dr. Rorig presented an extensive series of exhibits showing what chemists in the 1950s and 1960s knew of the effect of changing from a methyl to an ethyl group at various positions in the steroid nucleus. (Exhs. D-316-21). Changing from a methyl group to an ethyl group at the 17 position decreased the androgenicity in 17-alkyl 19-nordihydrotestosterones and in 17-alkyl testosterones. (Exhs. D-316-17). Changing the 6B methyl group to an ethyl group in a series of ethisterones rendered the molecule completely inactive as a progestin. (Exh. D-318).

*4 Similarly, changing the 21-alkyl group from a methyl to an ethyl reduced the progestational activity. (Exh. D-319); changing from a 2a methyl group to an ethyl group completely deactivated hydrocortisone (Exh. D-320), and changing from a 16a methyl to an ethyl decreased the activity of an anti-inflammatory agent by a factor of more than 20. (Exh. D-321). These results, known to chemists in the 1950s and early 1960s, suggested that replacing a methyl group with an ethyl group tended to decrease activity of steroid hormones.

15. Norgestrel and Norgestimate are progestins. In 1960, after stating that the state of the art did not allow accurate predictions of steroid activity (Tr. Rorig at 615), Dr. Ringold presented his hypothesis as to the shape of the progestin receptor lock and the progestin key which fits into that lock. He stated that:

Consideration of the progestational activity of a number of modified gestogens has lead us to propose that the "active" side of these derivatives is the a-face and the interaction at the target site where

the steroid is bound must be with a B-face of the progestational agent in order for the steroid to exhibit its basic effect. (Tr. Rorig 613-615).

16. According to Dr. Ringold's 1960 hypothesis, progestin activity required tight binding between the B-face of the progestin and the receptor. (Tr. Rorig 613-615). The 13-ethyl group in norgestrel, which is larger than the 13-methyl group of norethindrone, is pointing straight up from the B-face. (Exh. D-313). Dr. Ringold's theory would have predicted that 13-ethyl progestins would be less active than the natural 13-methyl compounds. (Tr. Rorig 619).

17. Dr. Victor Drill was the head of G.D. Searle's biological research and Dr. Byron Riegel was the head of Searle's chemical research in the 1950s and early 1960s. In 1957 they presented a paper at the Laurentian Conference on Steroid Research, a regular conference of eminent steroid scientists, at which the most recent developments in steroid research were discussed. They concluded:

It is obvious that activities can be separated by simple changes in structure and, secondly, that effects of structural change on endocrine activity cannot be predicted. (Tr. Rorig 638-39).

18. Dr. Doorenbos, Ortho's technical expert, did not disagree with the unpredictability in 1960 of steroid activity. Dr. Doorenbos testified that there was a general theory-not directed to steroids-under which it was believed that "there is the potential of increased activity." (Tr. Doorenbos 183). In some examples, the peak was with methyl; in some with higher homologues. However, as Dr. Doorenbos admitted, in steroids larger groups can unpredictably interfere with binding to the receptor site:

A. ... In literature, when people talk about steroids ... where larger groups were not active ... one of the hypotheses is that it's interfering with the absorption at that receptor site. And those things you can't predict. At least could not back in 1960. (Tr. Doorenbos 283).

*5 19. Dr. Doorenbos also admitted that the effects of structural change on hormone activity could not be predicted generally:

Q. And do you agree that the effects of structural change on endocrine activity cannot be predicted?

A. In the broad sense I would agree. You can anticipate and make educated guesses, but you never know for certain until the product is made and tested. (Tr. Doorenbos 291).

C. *The Differences Between the Claimed Invention and the Prior Art.*

20. Dr. Doorenbos testified that norgestrel was obvious from norethindrone, alone or in combination with the Belgian patents. His conclusion was based on a consideration only of the structures of the two molecules. However, Dr. Doorenbos did not consider the claimed compounds as a whole-in particular, he failed to consider the differences between the properties of norethindrone and norgestrel. (Tr. Doorenbos 300).

21. Although Dr. Doorenbos said it would be easy to modify the prior art syntheses to make norgestrel, no one did so prior to Smith and Hughes, and Dr. Rorig pointed out the difficulties that would have arisen due to unwanted side reactions and formation of isomers, even if one conceived of attempting to do so in the first place. (Tr. Rorig 600-602). [Dr. Doorenbos and his students never made a steroid by total synthesis (Tr. Doorenbos 244, 250).]

22. Biologically, the claimed compounds have properties which were unpredicted by, and unexpected in light of, the prior art. Whereas the prior art steroids with ethyl groups attached to the nucleus at various positions were generally less active than the corresponding methyl compounds, the 13-ethyl compounds of Smith and Hughes are generally more active. For example, norgestrel (specifically claimed by claim 5, and covered by generic claims 40 and 43 of the '322 patent) is approximately 100 times more potent than norethindrone (Exh. D-325); norgestrel acetate (specifically claimed as claim 19, and covered by generic claims 40 and 43) is 60 times more potent than the corresponding 13-methyl compound norethindrone acetate (Exh. D-323). Other

13-ethyl gon-4-enes which fall within the scope of claims 40 and 43 are also unexpectedly more potent than the corresponding methyl compounds. 21-choronorgestrel is almost 4 times more potent than the corresponding methyl compound (Exh. D-323), and norgestimate is roughly 3.5 times as potent as the corresponding methyl compound. (Exh. D-329). Two other 13-ethyl gon-4-enes which were recently marketed in oral contraceptives in Europe, gestodene and desogestrel, are more potent than the corresponding methyl compounds. (Exhs. D-326 and D-327).

23. The 13-ethyl gon-4-enes also exhibit an improved separation of biological activity over the 13-methyl compounds. Progestin analogs can exhibit androgenic effects, at least at very large doses in the laboratory. Separation of activity refers to the differences in dosages required to see a desirable effect and an undesirable effect. (Tr. Goldzieher 818, Phillips 991). Norgestrel exhibits more than 20 times better separation of desirable progestational effects and androgenic effects than norethindrone. (Exh. D-325). Similarly, gestodene exhibits a separation of activities twice that of the 13-methyl compound, as does 3-keto desogestrel. (Exhs. D-326 and D-327).

*6 The court finds that the above separations of desirable and undesirable activity were not predictable from the prior art. (Tr. Rorig 647, 650). Even in 1990, Ortho's rebuttal witness Dr. Phillips could not predict the properties of norgestrel acetate from the corresponding 13-methyl compound:

Q. ... The binding affinity of norgestrel acetate could not be predicted from the binding affinity for norethindrone acetate?

A. No. Without a significant structure activity relationship database, I would not be able to predict whether or not the addition of an acetate to a steroid might change any given biological activity. (Dep. Phillips 159-160).

24. Finally, norgestrel, unlike other oral contraceptives, does not exhibit a first-pass effect. This means that, while other oral contraceptives are partially chewed up in the liver before they get to the bloodstream, almost all of the noregestrel is available for hormonal action. (Tr. Goldzieher 834). Larger doses of drugs exhibiting a first-pass effect are required, because the first pass effect is extremely variable among different patients. Oral contraceptives containing norgestrel-but not norethindrone-can thus be designed to give good cycle control without excess medication. (*Id.*)

D. *Secondary Considerations of Non-Obviousness: Commercial Success.*

25. Prior to the introduction of defendants' first norgestrel-containing oral contraceptive (Ovral) in the U.S., all commercially available oral contraceptives included progestational agents derived from natural sources. (Tr. Hughes 538).

26. Since their introduction in 1968 into the U.S. market, U.S. sales of norgestrel products have been approximately 2.8 billion dollars. (Tr. Bogash 711). During the period 1968-1972, the market share for Ovral rapidly increased from approximately 2.5 percent of the U.S. oral contraceptive market in 1968 to over 20 percent of the market by 1972. Several years later, norgestrel products reached a level of over 30 percent of the U.S. market, at which point sales have leveled off. The percentage of new prescriptions being written for Ovral by 1972 likewise increased rapidly to close to 30 percent of the new prescriptions written in the U.S., while a number of competitors saw their percentage of new prescriptions for their products (containing progestins derived from natural sources) plummet. (Tr. Bogash 709). Norgestrel-containing oral contraceptive products are commercially available from Wyeth in the U.S. under the trademarks Ovral, Lo/Ovral, Ovrette, Nordette and Triphasil. (Tr. Bogash 702-711).

27. Defendant American Home Products sublicensed Schering A.G. to make use of, and sell, norgestrel-related products outside the U.S. in 1965. At that time, Schering A.G. was already the single largest hormonal manufacturing and research and development company in the world, and controlled 55 percent of the market for oral contraceptives in Europe. Norgestrel and norgestrel-related products comprise about 80 percent of the total foreign oral

contraceptive market. (Tr. Bogash 696, 704; Exhibit 271L, ¶ 17).

*7 28. The court finds that the commercial success of norgestrel products is primarily due to its merits as a progestational agent. Its success in the marketplace is extraordinary and is a strong indication of its benefits over prior progestational agents. A further indication of the benefits of norgestrel is the fact that it achieved its market share in the face of stiff competition from established oral contraceptive products. (Tr. Bogash 706-07).

29. All new oral contraceptives which have come onto the market after the introduction of norgestrel-containing products include a progestin having an ethyl group at the 13 position. Like norgestimate, which is within the scope of claims 40 and 43 of the '322 patent, and which is currently being marketed abroad, gestodene and desogestrel are 13-ethyl gon-4-enes which fall within the scope of claims 40 and 43. (Exh. P-113; Exh. D-271L; Tr. Phillips 1011-13).

30. The court finds that the pharmaceutical industry has, despite Ortho's vigorous arguments to the contrary, acquiesced in the validity of the '322 patent . A substantial number of large pharmaceutical companies were doing research in the steroid field, resulting in numerous interferences with the Smith-Hughes invention, and none of those companies ever introduced norgestrel or a norgestrel derivative in the U.S. Also, a sublicense in the U.S. has been granted under the patents in suit to Berlex Laboratories. (Dep. Berg. 62-69).

31. The court further finds that Claims 5, 19, 40, and 43 of the '322 Patent were not obvious.

II. *Double Patenting*

32. It is undisputed that AHP's norgestrel product will enjoy no more than 17 years of patent protection. (Tr. Gamson 433-35).

33. Ortho has not alleged that the subject matter of claims 5, 19 and 40 of the '322 patent would have been obvious over (or even overlap) the claimed subject matter of any of the references upon which it relies.

34. Ortho argues that claims of the '081 and '909 patents render claim 43 of the '322 patent invalid for double patenting. However, the compounds of the claims of the '081 and '909 patents, as illustrated in Plaintiff's Exhibits 128-B and 128-C, are not gon-4-enes and were considered by the Patent Office to be independent and distinct from the gon-4-enes of the '322 patent. That conclusion was not challenged by any expert at trial. Those compounds do not fall within the scope of claims 1, 40 or 43 of the '322 patent. (Tr. Gamson 436, Bjorge 870-71).

35. There is no evidence that the claims of the '081 and '909 patents would have been obvious from claim 43 of the '322 patent or that claim 43 of the '322 patent would have been obvious from the claims of the '081 or '909 patents.

36. Ortho also argues that claim 1 of the '322 patent is invalid for double patenting over U.S. Patent No. 3,502,699 (the '699 patent). However, the claims of the '699 patent do not disclose or suggest claims 1, 5, 19, 40 or 43 of the '322 patent, as admitted by Ortho's own expert. (Tr. Doorenbos 264-65). In addition, there is no evidence in the record that the claims of the '322 patent disclose or suggest the claims of the '699 patent.

*8 37. The terminal disclaimer voluntarily filed in the prosecution of the '322 patent prosecution merely fixes an earlier date certain upon which that patent expires-November 26, 1991. (Exh. P-19; Tr. Bjorge 873). The court finds that the disclaimer does not operate to tie the validity of the '322 patent to the validity of the '911 patent or any other patent. (Tr. Bjorge 874). Therefore, even if the '911 patent were invalidated for double patenting, the '322 patent would not be invalidated as a result.

38. During the course of obtaining the '911 patent, the Patent Office issued restriction requirements that led to certain subject matter being designated as independent and distinct inventions and thus placed

in separately filed applications that later issued as United States Patent Nos. 3,391,165 ('165 patent), 3,407,217 ('217 patent), 3,417,081 ('081 patent), and 3,547,909 ('909 patent). (Exh. P-18; Tr. Gamson 383-84, 398, 436). Pursuant to 35 U.S.C. § 121, none of these four patents can be used as a basis for invalidating the '911 patent for double patenting.

39. Ortho argues that when the restriction requirements were made, original claim 1 was limited to compounds having an aromatic A-ring, and that amendment of the claims should result in a forfeiture of the benefits of 35 U.S.C. § 121. The scope of original claim 1 of the '911 patent encompassed compounds having an aromatic A-ring as well as compounds having a nonaromatic A-ring according to established authorities, usage in issued patents and deposition testimony of those involved in obtaining the patent. (Tr. Rorig 582-589, 667-71,-Dep. Smith 117-19,-Dep. Bellino 75, Tr. Doorenbos 278,-Exhs. D-211, D-212, D-343).

40. The Examiner of the '911 application, Henry French, was an experienced examiner who also examined each of the other applications leading to the patents upon which Ortho now relies for its double patenting contentions. (Tr. Gamson 466-68; Bjorge 864, 891-92). Ortho's own patent expert testified that Examiner French knew which claims were issuing and which claims were being put into which cases. (Tr. Gamson 467-68). In fact, Mr. French was specifically made aware of the claims kept in the '911 case and the claims kept in the '714 case (the very claims Ortho bases its cyclopentanophenanthrene argument on). (Tr. Gamson 468).

41. Since claim 1 of the '911 application did not materially change in scope during prosecution (see Dep. Bellino 99 11. 4-8), and particularly in view of the Examiner French's full knowledge of all pertinent circumstances, AHP is entitled to the benefits of 35 U.S.C. § 121.

42. Even if the '911 patent were not entitled to the benefit of 35 U.S.C. § 121, the '911 patent claims would not have been obvious from the claims of the '165 patent, the '217 patent, the '081 patent, the '909 patent or U.S. Patent 3,519,714 (the '714 patent), as Ortho's own expert admitted. (Tr. Doorenbos 262-63).

43. The court finds that there is no evidence in the record to even question the statutory presumption that the claims of the '165 patent, the '217 patent, the '081 patent, the '909 patent or the '714 patent would not have been obvious from the '911 patent claims.

*9 44. Ortho received opinions of counsel dated January 1, 1976, January 22, 1976, April 18, 1977, and January 11, 1990 concerning validity of the '911 and '322 patents. (Exhs. P-202, P-203, P-204; Exh. D-344). None of these opinions mentioned double patenting as a possible basis for invalidity, even though all the Smith and Hughes patents now relied on by Ortho were available at all pertinent times. (Tr. Gamson 433).

45. Throughout the entire preliminary injunction proceedings in this litigation Ortho never raised double patenting as a potential invalidity defense. Ortho's responses to AHP's First Set of Interrogatories, filed on or about March 12, 1990, set forth Ortho's contentions concerning validity. Double patenting was not mentioned. (Exh. D-271I). AHP deposed Benjamin Lambert, a J & J patent attorney, on April 27, 1990 pursuant to Fed.R.Civ.P. 30(b)(6) in an attempt to determine Ortho's invalidity contentions for trial. (Dep. Lambert 4/27/90). Double patenting was not raised. It was not until the eve of trial that Ortho finally raised this last minute defense.

46. None of the double patenting references Ortho relies on are available as prior art for anticipation purposes. They are only available, if at all, for use in an obviousness-type double patenting inquiry. (Tr. Bjorge 937-38).

III. *Inequitable Conduct*

47. At the time the application for the '911 patent was filed, patent examiners would review the oath with the particular purpose of seeing whether early issuing patents in foreign countries were referred to therein. (Tr. Bjorge 854).

48. A Belgian patent issues and is published a very short time after it is filed, i.e., six months or less, from its filing date. The quick publication of Belgian patents was known to examiners during the period in which the '911 patent was prosecuted. Belgian patents were a prime source of prior art information for Patent Examiners. (Tr. Bjorge 855-859; Gamson 441-42; Exh. D-267).

49. The Oath which was filed with the application which led to the '911 patent included a section citing a number of related foreign patents and a separate section citing a number of related foreign applications. (Exh. P-18 at 368-374; Exh. D-273A).

50. The Belgian patents cited in the oath are identified by country, patent number and filing date. Immediately prior to this section, the oath (for the '911 patent) states that "the said invention has not been patented before the date of said application in any country foreign to the United States on an application filed by us or our legal representatives or assigns more than twelve months prior to said applications, except as follows:". Belgian patent Nos. 595,384; 595,385 and 595,386 are cited immediately after this statement. Thus, the court finds that the subject matter of the Belgian patents is clearly identified as the invention of Smith and Hughes-i.e., a polycarbon alkyl group at C-13. The filing date of these Belgian patents is stated as September 23, 1960. (Exh. P-18 at 368; Exh. D-273A; Tr. Gamson 444).

*10 51. The stated filing date of these Belgian patents would have indicated a publication date of March 1961 to a patent Examiner. (Tr. Bjorge 856-860; Exh. D-267).

52. When the Examiner was searching for prior art, foreign patent references such as these Belgian patents were available to him, as well as translations of the same. (Tr. Bjorge p. 860-861). Copies of all of the British patent applications that Smith and Hughes relied on for priority purposes were provided to the Patent Office. (Exh. P-18 at 510-11). Each of the Belgian patents are stated to be based on the Smith and Hughes British patent applications. (Exh. P-8, pp. 1-2).

53. Belgian patent No. 595,386 was also cited in an amendment filed during the course of the proceedings for the '911 patent. This amendment, which was "suggested by the Examiner," added an additional claim for the purpose of declaring an interference. It is noted in this paragraph that Belgian patent 595,386 had an effective date of March 23, 1961. A copy of this Belgian patent was submitted along with this Amendment. The Belgian patent stood out as the sole reference cited in this letter amendment. (Tr. Bjorge 862; Exh. P-18 between 453 and 454 and 502-3; Exh. D-273B).

54. The Belgian patents were brought to the attention of the Patent Office on another occasion, in a reply brief filed during one of the four interference proceedings in which the '911 patent was involved. The brief cites three Belgian patents as prior art against third parties showing a method of the total synthesis of a species of a C-13 polycarbon steroid of the type relied upon by plaintiff as an alleged anticipation of claims 1-4 of the '911 patent. The brief on page 4 sets forth a specific compound which has a propyl group at the C-13 position which can be made by the process of the Belgian patent:

It can also be prepared from (±)-8-dehydro-13-n-propyl-oestradiol 3-methyl ether according to the method of British Application 32671/60 ... a method for the total synthesis of the latter compound being known in the prior art. (Belgium Patents 595,384; 595,385; 595,386 and 600,244, all open for public inspection prior to 1961 Oct. 19). (Tr. Bjorge 862-864; Exh. D-250A).

55. During the four interferences in which application for the '911 patent was involved, the citation of prior art to the Patent Office was appropriate. Prior art was considered by the primary examiner during the interference (Tr. Bjorge 934), including Belgian and other patents and publications available in 1961. (Exh. D-250B).

56. Defendant American Home Products' in-house patent counsel, who had overall responsibility for the procurement of the '911 patent, testified that he

was sure that he and outside counsel who assisted in the procurement of the '911 patent had done everything they could within the rules and law and never did anything to deceive or conceal anything. To this, plaintiff's counsel responded that no implication was being made that Dr. Bellino did anything to deceive. (Dep. Bellino 141).

*11 57. The issue of when Hughes and Smith made their invention was raised several times during the interference proceedings in connection with obtaining the '911 patent. Hughes and Smith conceived of their invention in the period of 1959 to 1960, as stated in several papers filed in the Patent Office, well prior to the date of the Belgian patents were published. (Exhs. P-18 379-80, 424-27, 441, 453; D-250A, B, C, D and E). Despite the fact that others attacked the Smith and Hughes application based on foreign patents and publications dated 1961 (Exh. D-250B), none raised these Belgian patents as a bar to patentability.

58. Although the issue of when Smith and Hughes made their invention was raised in the Patent Office proceedings, and although third parties had the opportunity to, and did cite subsequently issued references, the Patent Office officials concluded that there was no impediment to the issuance of the '911 patent and there is no evidence that AHP considered the Belgian patents a bar to patentability any more than did the Patent Office or third parties.

59. Ortho has also sought to raise a new issue of inequitable conduct at trial which was not raised prior to trial or in plaintiff's case in chief. Ortho contends that defendant engaged in inequitable conduct by not including in an affidavit a single piece of published data relating to the androgenic effects of norgestrel (published in 1963, Exh. P-193) when presenting favorable progestin data to the Patent Office during the proceedings which led to the issuance of the '322 patent. (Tr. 955-56).

60. The court finds that the uncontroverted testimony of the defendants' experts weighs strongly on this issue. Dr. Rorig testified that although androgenic activity is increased slightly in moving from the methyl to the ethyl moiety, the ethyl compounds show a substantially greater separation between progestational and androgenic activities, thereby enhancing the desirable properties of the claimed compounds. (Tr. Rorig 648-650, 653, 662). Dr. Goldzieher testified that the androgenic side effects of norgestrel as well as norgestimate have no clinical significance. (Tr. Goldzieher 821-826). Mr. Bjorge testified that the androgenic data should not be presumed to be material, and that absent its materiality, there was no inequitable conduct. (Tr. Bjorge 910). There was no testimony, nor any expert opinion, on any intent to deceive.

IV. *Infringement*

A. *Ortho Has Admitted Infringement of Claims 40 and 43*

61. Ortho has admitted infringement of claims 40 and 43. (Ortho's Response to AHP's First Set of Requests to admit Nos. 6 and 7, Exh. D-271L; Tr. Gamson 426; Dep. Lambert 36-38).

B. *Claims 5 and 19 are Infringed Under the Doctrine of Equivalents*

1. *Norgestimate Was Created From Norgestrel*

62. Norgestimate was initially made from norgestrel by Dr. Arvin Shroff of Ortho, who was identified as the inventor of norgestimate. (Exh. D-25, 29; Exh. P-239). Dr. Shroff did not know how to make norgestrel; he used a bottle of norgestrel he had obtained from his stockroom. He used basic laboratory techniques known to undergraduate students in the 1950s, and the whole process took less than a day. (Dep. Shroff 30-33, 101; Exh. D-19 at 89-91; Tr. Rorig 602-604; Tr. Doorenbos 238-39). Dr. Shroff also made the corresponding 13-methyl compound, norethindrone acetate oxime, which is covered by the same Ortho patent which covers norgestimate. (Dep. Shroff 27; Exh. D-31, claim 2). The 13-methyl compound was tested by Ortho and discarded in favor of norgestimate, the 13-ethyl compound. (Exh. D-244 at 21-22). Steroidal oximes were known to be able to exhibit hormonal activity. (Exh. D-197, column 3, lines 20-25). Dr. Shroff obtained three patents covering

norgestimate. (Exhs. D-25, D-29, D-31). The first issued in 1970 (Exh. D-29), and the last expires in 1994. (Exh. D-25).

*12 2. Norgestimate Is Converted to Norgestrel and Norgestrel Acetate in the Body, Which Are Responsible for the Progestational Activity of Norgestimate

63. In 1984, Alton, at Ortho, prepared an internal report on the urinary metabolites of norgestimate (Exh. D-23), and published some of the data. (Exh. D-104). Norgestimate is rapidly and extensively metabolized (broken down) in the body to a variety of "metabolites." (Tr. Jusko 732, 735; Exhs. D-23 at pages 12-13, D-295, D-305, D-307).

64. Hormone metabolites can be extracted from the urine of women following oral administration of either norgestrel or norgestimate. The urinary metabolite patterns show similarities from which it can be concluded that norgestimate is being metabolized to norgestrel in a woman's body, and norgestrel is further being metabolized. (Tr. Jusko 734-36; Exh. D-305).

The results of this study suggest that the biotransformation of norgestimate is comparable to that of norgestrel ... norgestrel was recovered in urine following the oral administration of both norgestrel and norgestimate. The relative amounts of norgestrel, however, were different. ... This difference, however, as well as other minor differences, are probably not significant. (Exh. D-23 at page 13).

65. A hormone (or its metabolites) deliver their chemical message by being transferred through the blood stream ("serum") to the receptor site. (Tr. Jusko 785). The activity of a hormone (or its metabolites) is the product of its potency times its concentration. (Tr. Jusko 788; Exh. D-296). A hormone which is not present in the bloodstream cannot function as a hormone. (Tr. Jusko 747).

66. Ortho conducted an experiment in 1977 to measure the levels of norgestimate's metabolites in the blood. (Exh. D-107). Using state-of-the-art techniques (Tr. Jusko 740; Dep. Phillips 86), Ortho determined that norgestimate's three pharmacologically active metabolites were present in the following amounts:

Norgestrel oxime	10.6%	±	1.8%
Norgestrel acetate	9.5%	±	1.7%
Norgestrel	15.4%	±	5.4%

The amount of norgestimate could not be accurately measured because of interference with other metabolites. At most, it could have been 6.2% ± 1.5%. It could have been zero. (Tr. Jusko 739). Norgestrel acetate is the species of claim 19; norgestrel is the species claimed in claim 5.

67. In 1989 Ortho measured the amount of norgestimate in the bloodstream of women who had been given norgestimate. It was minuscule at best (less than 0.4% that of a comparable dose of norgestrel) and had completely disappeared from the blood stream within 6 hours. (Tr. Jusko 743-745; Exh. D-187 at 28).

68. Dr. Jusko calculated the progestational effect of the low levels of norgestimate and norgestrel oxime present in the blood by multiplying the low concentrations times the relative potencies measured by Ortho. (Tr. Jusko 751; Exhs. D-296, D-335), and comparing those effective concentrations to the known effective concentration of norgestrel. (Tr. Jusko 752-3). He concluded that the amount of norgestimate and norgestrel oxime is too small to account for the biological activity or norgestimate (Tr. Jusko 788, 753, 793), and that the activity of norgestimate is primarily due to norgestrel and norgestrel acetate (Tr. Jusko 768), and in fact, up to 85% of the activity is due to norgestrel acetate. (Id. 753).

*13 Q. What do you conclude from the data on Exhibit 296?

A. If you see the concentrations of norgestrel, how high they are, and then assess how low the concentrations or norgestimate and norgestrel oxime are when related as the effective concentration, one would conclude that there isn't sufficient amount of progestin from these two compounds to account for the activity or norgestimate.

Q. What in your opinion is causing the progestational activity of ingested-of norgestimate which a woman takes orally?

A. Based on the metabolic data that we covered previously, I would conclude that it's got to be the norgestrel and the norgestrel oxime that makes up the difference.

Q. And norgestrel acetate, is that also part-

A. I'm sorry. And norgestrel acetate is what I meant that makes up the difference.

Q. How much of the activity or norgestimate oral contraceptive do you believe is due to norgestrel and norgestrel acetate?

A. Because of the differential of the curves in the diagram, my estimate is that it may be as much as 85 percent of the dose must be accounted for from the activity of norgestrel and norgestrel acetate.

Q. Is it your understanding that norgestrel oxime is in fact the active ingredient of norgestimate?

A. No. It's one of several active compounds.

Q. It's one of several. Do you consider it to be a primary source of progestational activity of norgestimate?

A. No, it's too weak to be a primary source. The primary sources would have to be norgestrel or norgestrel acetate. (Tr. Jusko 752-753, 768).

Dr. Jusko's analysis and opinions were not rebutted.

3. Norgestimate Functions in the Same Way as Norgestrel in Oral Contraceptives to Give the Same Result

69. Progestins, such as Ortho's norgestimate and Wyeth's norgestrel, function in three ways in an oral contraceptive. First, they shut down the production of two other hormones, FSH and LH, in the hypothalamus and pituitary gland, preventing ovulation. Second, they change the lining of the endometrium so that it is less favorable to the implantation of a fertilized egg. (Tr. Goldzieher 803). Both norgestimate and norgestrel function in the same way. (Id.; Ortho's response to AHP's Interrogatory No. 20; Exh. D-271I).

The mechanism of action of norgestimate and norgestrel is the same: they both bind to progestational receptors and induce a progestational response. (Exh. D-271I at 14).

70. There are a number of pre-clinical tests which measure the activity of a compound as a progestin. In test after test for measuring progestins, norgestrel and norgestimate functioned as progestins to give substantially the same overall result, as admitted by Ortho and confirmed by Dr. Goldzieher. (See generally Exh. D-300; Tr. Goldzieher 805-818; Exhs. D-133, D-172, D-153, D-155, D-164, D-182).

71. While progestins can exhibit androgenic effects in pre-clinical tests, they do not do so clinically in combination oral contraceptives. (Tr. Goldzieher 818).

*14 72. Typically, progestins exhibit a separation of progestational and androgenic activity. (*Id.*) This means that at some low dose the progestin will exhibit progestational activity, whereas at a higher dose it may exhibit androgenic activity. (Tr. Phillips 992-995). If the separation of activity is high enough, no androgenic effect will be observed at the low progestational dose. (Tr. Goldzieher 807, 818-832, 838-842; Exhs. D-133, D-177).

73. Overall, norgestimate and norgestrel perform essentially the same function in essentially the same way, with essentially identical results in oral contraceptives. (Tr. Goldzieher 832; Tr. Jusko 768, 753).

C. *Infringement Under 35 U.S.C. § 271(e)(1)*

74. On June 4, 1990, this court preliminarily ordered that J & J and Ortho be enjoined from transmitting to any foreign affiliate or third party any data based on the manufacture, use, or sale of norgestimate, and from profiting from the use of such data except to submit it to the United States Food and Drug Administration.

75. In 1986, J & J's foreign affiliate, Cilag A.G., received approval to market norgestimate in Germany (Exh. D-113 at 3). In 1987 the BGA, the German drug regulatory agency, requested that Cilag conduct certain animal studies using norgestimate. Ortho requested that Hazelton Laboratories, located in the United States, use norgestimate to generate the requested data. The data were then filed with the BGA in Germany, and with the FDA in the U.S. (Exh. P-271M, ¶ 4(c); Tr. Phillips 1014).

76. Ortho has had a policy of sending any information it submits to the FDA under its New Drug Application ("NDA") to foreign affiliates of J & J for their use in seeking registration in their countries. (Dep. Hilke 48). In addition, data developed for purposes of a foreign registration is also sent to the FDA, regardless of whether or not such testing is needed for FDA approval. (Dep. Barba 19; Exh. D-57, D-72). Clinical, toxicology, pharmacology, drug distribution, absorption, mutagenic and preclinical data have been sent to foreign affiliates of J & J. (Exh. P.271L, ¶ s 18-24).

77. The court finds that Ortho has used test data submitted to the FDA for promotional and marketing purposes in the United States and overseas. (Dep. O'Neil 27; Exhs. D-12, D-13, D-45, D-50, D-86, D-87, D-97, D-106).

D. *Willful Infringement*

78. On February 6, 1976 and April 18, 1977, Ortho received opinions from patent counsel to the effect that both the '911 and '322 patents were, in their

opinion, invalid and unenforceable. (Gamson Tr. 419-427; PX-202, 203).

79. Ortho relied upon the opinion of counsel. The court finds that the infringement by Ortho was not willful and that no circumstances exist to warrant a finding that Ortho's actions were exceptional.

E. *Johnson & Johnson has Committed Acts of Infringement*

80. Pharmaceutical Research Institute is also referred to as the R.W. Johnson Institute. (Dep. Hilke 1/24/90 9). PRI departments include clinical research, drug metabolism, drug safety and pharmaceutical research. PRI conducts basic research and clinical studies for Ortho and does whatever is necessary for norgestimate to be registered with the FDA and to be manufactured. PRI is also responsible for presenting the results of clinical trials at medical meetings. (Dep. Hilke 1/24/90 13-16; Dep. Barba 1/24/90 21-22).

***15** 81. PRI is responsible for sending NDA information to affiliate European companies seeking registration in their countries, and providing regulatory support to Cilag (J & J's European subsidiary) in a number of areas including pharmacology, drug distribution, drug metabolism, and pharmaceutical development. (Dep. Hilke 3/28/90 48, 52-55; Exh. D-56).

82. Mr. Benjamin Lambert is a patent attorney employed by J & J who provides patent legal services to Ortho, including advice about the '322 patent. (Tr. Gamson 422-423; Dep. Lambert 1/24/90 4).

83. J & J has admitted that Ortho made a norgestimate-containing oral contraceptive and that PRI participated in obtaining FDA approval for the product. (J & J's Answer to AHP's Counterclaim ¶ 11).

CONCLUSIONS OF LAW

The Court's earlier holdings on the issues considered on the hearing for the preliminary injunction in this matter are adhered to, except as modified herein. *Yonkers Raceway v. Standardbred Owners Ass'n.*, 21 F.R.D. 3, 6 (S.D.N.Y.1957).

This court will not consider any of the questions decided on the hearing for a preliminary injunction as res judicata. They are open for review, but they should be adhered to, unless it clearly appears that an error was committed, or that additional facts were brought out at the trial which demand a modification or reversal of the views expressed at the preliminary hearing.

See also, Travelers International AG v. TransWorld Airlines, 722 F.Supp. 1087, 1090 (S.D.N.Y.1989), *Independent News Co. v. Williams*, 273 F.Supp. 375, 376 (E.D.Pa.1967).

I. *Validity*

A. *Burdens and Presumptions*

1. The Patent Statute, 35 U.S.C. § 282, is unambiguous:

"A patent shall be presumed valid ... [T]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."

Accordingly, a patent is born valid. *Roper Corp. v. Litton Systems, Inc.*, 757 F.2d 1266, 1270 (Fed.Cir.1985). *See also Datascope Corp. v. SMEC, Inc.*, 776 F.2d 320, 323 (Fed.Cir.1985). Each claim of the patent is presumed valid independently of every other claim. *Preemption Devices, Inc. v. Minnesota Mining and Mfg. Co.*, 732 F.2d 903, 907 (Fed.Cir.1984).

2. Defendants' burden of proving invalidity is a heavy one, and must be carried by clear and convincing evidence proving facts compelling a conclusion of invalidity. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed.Cir.1986), *cert. denied*, 480 U.S. 947 (1987); *SSIH Equipment, S.A. v. U.S. Inter. Trade Comm'n*, 718 F.2d 365, 375 (Fed.Cir.1983).

3. "Clear and convincing evidence" is "evidence which produces in the mind of the trier of fact 'an abiding conviction that the truth of [the] factual contentions are 'highly possible.' " *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed.Cir.1988) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

4. Patentees do not have any burden to prove any facts compelling a conclusion of validity, *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1555, (Fed.Cir.1985) and the court need not make such a finding. *Jones v. Hardy*, 727 F.2d 1524, 1528-29 (Fed.Cir.1984).

***16** 5. The party asserting invalidity not only has the procedural burden of proceeding first and establishing a prima facie case, but the burden of persuasion on the merits remains with that party until final decision. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed.Cir.1983).

6. The infringer's already heavy burden of proving invalidity is more difficult to overcome when the evidence relied upon consists only of the prior art considered by the patent Examiner or when the prior art asserted is no better than that which was before the Examiner when he decided to grant the patent. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed.Cir.1984). *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1087, 1096, *cert. granted, vacated*, 475 U.S. 1809, *on remand*, 810 F.2d 1561, *cert. denied* 481 U.S. 1052 ("Nor is it the court's role to start from scratch, as a surrogate Examiner, to referee *de novo* a dispute on the validity of the question."); *Polaroid v. Eastman Kodak Co.*, 789 F.2d 1556, 1560 (Fed.Cir.), *cert. denied*, 479 U.S. 850 (1986).

7. Mr. Gamson, Ortho's witness on double patenting, was also Ortho's counsel on the subject of this litigation up to the present and zealously represented his client to the limit of the law. (Tr. Gamson 454). It is error to invalidate a patent on the opinion of a lawyer associated with a party. *Universal Athletic Sales Co. v. American Gym*, 546 F.2d 530, 540 and n. 27 (3d Cir.1976) ("[T]he district court erred when it placed controlling weight as to patent validity, on the opinions of a lawyer associated with defense counsel. In so holding, we express doubt that the heavy presumption of patent validity can be overcome by the testimony of an attorney on behalf of his client.")

B. *Obviousness*

1. *The Legal Standard*

8. In *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), the Supreme Court set forth the basic framework for analyzing obviousness:

Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in pertinent art resolved. Against this background, the obviousness or nonobvious-ness of the subject matter is determined.

2. *Objective Criteria of Non-Obviousness*

9. The marketplace response to a patented invention often provides a significant indication of the non-obviousness of an invention. *See Graham*, 383 U.S. 1, 17-18. In such cases, "secondary considerations" supply objective evidence of how a patent is viewed by those directly interested in a patented product. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed.Cir.), *cert. denied*, 109 S.Ct. 395 (1988). These secondary considerations, which include commercial success, long-felt need for the invention, failure of others, and acquiescence of the industry, are an essential and integral part of determining obviousness. *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1498 (Fed.Cir.1986). A license indicates a decision to pay tribute to the invention. *See In re Geiger*, 815 F.2d 686 (Fed.Cir.1987). Once the patentee shows significant sales of the patented product the burden of rebuttal is on the challenger to show that the commercial success was due to extraneous factors other than the merit of the patented invention, *Demaco* 851 F.2d at 1392-93.

***17** 10. The objective indicia of nonobviousness (the "secondary considerations" of Graham) are

usually the most important items of evidence available and are properly viewed as a "fourth" factual inquiry in the *Graham v. Deere* investigation. *Simmons Fastener Corp. v. Illinois Tool Works, Inc.*, 739 F.2d 1573, 1575 (Fed.Cir.1984), *cert. denied* 471 U.S. 1065 (1985).

"[S]econdary considerations may be the most pertinent, probative, and revealing evidence available to the decision maker in reaching a conclusion on the obviousness/non-obviousness issue....

Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 306 (Fed.Cir.1985), *cert. denied*, 475 U.S. 1017 (1986).

3. *Obviousness and Chemical Compounds*

11. Chemical compounds and their properties are inseparable and there is no basis in law for ignoring any property in making a comparison. *Jones v. Hardy*, 727 F.2d 1524, 1528-30 (Fed.Cir.1983); *In re Papesch*, 315 F.2d 381 (CCPA 1963).

Section 103 says, inter alia, 'The subject matter as a whole would have been obvious....' Nothing is said about 'obvious to try.' Consideration of the subject mater 'as a whole' in chemical cases requires comparison of properties, pharmaceutical or otherwise, as well as comparison of chemical structures.

In re Huellmantel, 324 F.2d 998 (CCPA 1963). "If the patent law were to define a drug solely by its chemical structure, few new drugs would be patentable." *Eli Lilly and Co. v. Premo Pharmaceutical Labs*, 630 F.2d 120, 127 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980) (upholding Eli Lilly's patent on a pharmaceutical).

12. New chemical compounds are entitled to patent protection if their properties are unexpectedly different from, or superior to, those of compounds described in the prior art. *See, e.g., In re Chupp*, 816 F.2d 643, 645-46 (Fed.Cir.1987).

13. The properties of the new compound need not be completely different from those of the prior art to merit patent protection. Rather, it is sufficient to produce "[e]vidence that (the) compound is unexpectedly superior in one of a spectrum of common properties...." *In re Chupp*, 816 F.2d at 646; *Accord Eli Lilly & Co. v. Premo Pharmaceutical Laboratories*, 630 F.2d 120, 131 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980). Such superiority need not consist of properties lacking in the prior art compounds. *Id.* If the superior property of the new drug has led to its acceptance in the medical community, the compound's superior property is a "significant enough contribution to be deserving of a patent." *United States v. Ciba-Geigy Corp*, 508 F.Supp. 1157, 1169 (D.N.J.1979).

4. *Policy Considerations*

14. The policy rationales behind the patent statutes generally apply with even greater strength in the case of drug patents. It is in the public interest to protect the pharmaceutical industry's investment into the discovery of new drugs.

***18** As the record in this case indicates, the development and perfection of new drugs frequently requires the devotion of years of research time and the expenditure of millions of dollars.... Unless this type of an investment of human and capital resources is rewarded by some form of patent protection, companies such as Eli Lilly might well choose not to undertake such large expenditures and instead devote themselves to other endeavors. To the extent this occurs, resources would be diverted from activity that is socially beneficial-the development of new drugs. As one commentator has put it, 'Viewed in these terms, the patent grant ... functions as a means of raising the expected return to be gained from basic drug research sufficiently to overcome the investor firm's risk aversion and induce it to invest additional funds in research instead of alternative investment opportunities such as production process improvement programs, advertising, increased customer service, or the like.'

Eli Lilly and Co. v. Premo Pharmaceutical Laboratories, 630 F.2d 120, 137-38 (3d Cir.), *cert. denied*, 449 U.S. 1014 (1980) (footnote omitted).

The public likewise has an interest in promoting large numbers of drugs which perform the same basic function, so that alternatives are available for individual therapy.

Knowledge of the pharmacological activity of any compound is obviously beneficial to the public. It is inherently faster and easier to combat illnesses and alleviate symptoms when the medical profession is armed with an arsenal of chemicals having known pharmacological activities. Since it is crucial to provide researchers with an incentive to disclose pharmacological activities in as many compounds as possible, we conclude that adequate proof of any such activity constitutes a showing of practical utility. *Nelson v. Bowler,* 626 F.2d 853, 883 (CCPA 1980).

Accord Cross v. Iizuka, 753 F.2d 1040, 1044 (Fed.Cir.1985).

C. *Double-Patenting*

15. There are two types of double patenting: (1) same invention double patenting and (2) obviousness-type double patenting. *In re Longi,* 759 F.2d 887, 892 (Fed.Cir.1985). Ortho does not allege same invention double patenting in this case. (Tr. Gamson 457).

In the latter situation ("obviousness"-type), the test is whether the subject matter of the claims of the patent sought to be invalidated would have been obvious from the subject matter of the other patent, and vice versa. In considering that question, the disclosure of the "reference" patent may not be used as prior art.

Carman Indus., Inc. v. Wahl, 724 F.2d 932, 940 (Fed.Cir.1983); *See also Phillips Petroleum Co. v. United States Steel Corp.,* 604 F.Supp. 555 (D.Del.1985), *later proceeding,* 673 F.Supp. 1278 (D.Del.1987), *aff'd* 865 F.2d 1247 (Fed.Cir.1989).

16. The presumption of validity not only applies to double patenting allegations, it imposes "a heavy burden of proof on one seeking to show double patenting." *Carman Indus.,* 724 F.2d at 940. That burden is even more difficult to overcome where, as here, the same Examiner allowed each of the patents at issue. 2 Rosenberg, *Patent Law Fundamentals,* § 1505, at 15-88.8 (1990).

***19** 17. There can be no obviousness-type double patenting where there is no determination of obviousness. The court, in *Studiengesellschaft Kohle mbh v. Northern Petrochemical Co.,* 784 F.2d 351 (Fed.Cir.) *cert. dismissed,* 478 U.S. 1028 (1986), dealt with just such a situation:

The district court made no findings as to obviousness-type double patenting. We agree with SGK that Northern Petrochemical offered *no evidence* of the scope and content of the pertinent art, other than the '115 patent, the level of skill in the art, or what would have been obvious to a person skilled in the art. *Consequently, we hold that obviousness-type double patenting is not involved in this case. Id.* at 355 (emphasis added).

The issue on double patenting is obviousness, not merely whether the claims of one patent dominates the claims of another. *In re Kaplan* 789 F.2d 1574, 1577 (Fed.Cir.1986) (" 'domination' which by itself does not give rise to 'double patenting' ").

18. Ortho's attempts to tie the validity of claim 1 of the '322 patent as well as the claims of the '911 patent to the validity of claims 5, 19, 40 and 43 of the '322 patent run contrary to the explicit directives of 35 U.S.C. § 282.

Each claim of a patent (whether in independent, dependent or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent on an invalid claim.

35 U.S.C. § 282. Each claim of a patent is considered its own invention, and must be proven invalid independent of the validity of any other claims or patents. *See Shelcore, Inc. v. Durham Indus, Inc.,* 745 F.2d 621, 625 (Fed.Cir.1984). (It is a "requirement at trial that a party challenging the validity of a claim, absent a pretrial agreement or stipulation, must submit evidence supporting a conclusion of invalidity of *each* claim the

challenger seeks to destroy.") (emphasis in original). *Ashland Oil, Inc. v. Delta Oil Prods. Corp.*, 685 F.2d 175, 178 (7th Cir.1982) (where only some claims of patent are proven invalid for double patenting, it is reversible error to invalidate other claims of the patent), *cert. denied*, 460 U.S. 1081 (1983).

19. Matter not within the scope of a claim is often cited and used to show support for that claim under 35 U.S.C. § 112. *See, e.g., Heymes v. Takaya*, 6 U.S.P.Q.2d 1448, 1452 (P.T.O. Bd.Pat.App.. & I.), *reconsideration denied*, 6 U.S.P.Q.2d 2055 (P.T.O. Bd.Pat.App. & I. 1988). Specific embodiments of the invention of a claim may be found in the disclosure *considered as a whole. In re Honn*, 364 F.2d 454, 460 (C.C.P.A.1966).

20. AHP is entitled to the benefits of 35 U.S.C. § 121, which provides that when the Patent Office requires restriction between several groups of claims, and divisional applications are filed as a consequence, the resulting patents are not available for an obviousness-type double patenting defense against each other.

***20** 21. Even if the '911 patent were invalid for double patenting, the '322 patent would not be invalidated as a result. While the '322 patent is terminally disclaimed to expire on the same date that the '911 patent is set to expire, the validity of the '322 patent is not inextricably tied to the validity of the '911 patent. All patents are presumed valid under 35 U.S.C. § 282, not just those patents which do not have a terminal disclaimer. *Bausch & Lomb, Inc. v. Barnes-Hind Hydrocurve, Inc.*, 796 F.2d 443 (Fed.Cir.1986), *cert. denied*, 484 U.S. 823 (1987). Invalidity cannot be imposed merely because a related patent may be invalid.

22. Judge Learned Hand spoke to the above issue in *H.C. White Co. v. Morton E. Converse & Son Co.*, 20 F.2d 311 (2d Cir.), *cert. denied*, 275 U.S. 547 (1927).

> Whatever may be the result if throughout the granted term the inventor had the enjoyment of his apparent monopoly, it seems to us that, when his patent is declared invalid before its expiry, the consideration fails and the counter consideration moving from the inventor-i.e., the dedication of the disclosure-may be revoked. There being no chance for apportionment of the dedication, *it ought not therefore be held that a subsequent and valid patent is itself invalidated because of the original dedication.*

20 F.2d at 314 (emphasis added). *See also Shelcore, supra*, 745 F.2d 621 (later design patent terminally disclaimed over earlier utility patent; even where 12 of the 13 claims of utility patent were invalidated, design patent no invalid *Gemveto Jewelry Co. v. Jeff Cooper Inc.*, 694 F.Supp. 1085 (S.D.N.Y.1988) (later issued patent terminally disclaimed over earlier patent; even where later patent was invalidated, earlier patent remained valid *aff'd without op.*, 884 F.2d 1399 (Fed.Cir.1989).

23. The court concludes, on the basis of the foregoing, that the plaintiff in this case has failed to prove by clear and convincing evidence that the defendants' patent is invalid. Accordingly, the court finds that the defendants' patent remains valid and must be accorded the protection enjoyed by all valid patents until their full term has expired.

II. *Inequitable Conduct*

24. Inequitable conduct must be proved by clear and convincing evidence, and the party asserting it carries a heavy burden. *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed.Cir.1984); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed.Cir.1983); *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 698 (Fed.Cir.1983) *cert. denied*, 464 U.S. 1043 (1984).

25. A finding of inequitable conduct during the prosecution of a patent requires proof by clear and convincing evidence of both (1) the materiality of the prior art withheld from the patent examiner; and, (2) an intent to deceive the examiner. *Specialty Composites v. Cabot Corp.*, 845 F.2d 981, 991-3, (Fed.Cir.1988); *FMC Corp. v. Manitowoc Co.*, 835 F.2d 1411, 1415, (Fed.Cir.1987).

*21 26. "To be guilty of inequitable conduct, one must have intended to act inequitably." Thus, one who alleges a "failure to disclose" form of inequitable conduct must offer clear and convincing proof of failure of the applicant to disclose art or information resulting from an intent to mislead the PTO. *In re Harita,* 847 F.2d 801, 809 (Fed.Cir.1988). Even conduct that amounts to " gross negligence" does not of itself justify an inference of intent to deceive. *Kingsdown Medical Consultants, Ltd., et al. v. Hollister, Inc.,* 863 F.2d 867, 876 (Fed.Cir.1988), *cert. denied* 109 S.Ct. 2068 (1989).

27. Absent intent to withhold information, it is not controlling whether the reference is found to anticipate or otherwise to be material. *Allen Organ Co. v. Kimball Int'l., Inc.,* 839 F.2d 1556, 1568 (Fed.Cir.), *cert. denied* 109 S.Ct. 132 (1988). Inequitable conduct cannot lie when "applicant's failure to disclose art or information did not result from an intent to mislead the PTO. *FMC v. Manitowoc,* 835 F.2d at 1415.

28. The involved conduct, viewed in light of all of the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive. *Kingsdown, supra.*

29. Inequitable conduct is a much-abused and too often last-resort allegation. *Preemption Devices v. Minn. Min & Mfg. Co.,* 732 F.2d 903, 908 (Fed.Cir.1984). As in many patent cases, the issue of inequitable conduct deflects the court's attention from the issues of validity and infringement. *In re: Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions,* 538 F.2d 180, 196 (8th Cir.1976) *cert. denied,* 429 U.S. 1040 (1977). An infringement defendant in complex litigation should not be permitted to sidestep these main issues by nit-picking the patent file in every minute respect with the effect of trying the patentee personally, rather than the patent. *Id.* As recently stated:

[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interest adequately, perhaps. They get anywhere with the accusation in but a small percentage of cases.

Burlington Indus., Inc. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed.Cir.1988).

30. After careful review of all the evidence presented, the court concludes that plaintiff has failed to demonstrate that defendants engaged in inequitable conduct.

III. *Infringement*

A. *Burdens and Presumptions*

31. Infringement is a question of fact. *Windsurfing Int'l, Inc. v. AMF, Inc.,* 782 F.2d 995 (Fed.Cir.), *cert. denied,* 477 U.S. 905 (1986). Infringement is established by a preponderance of the evidence. *Jamesburg Corp. v. Litton Indus. Prods., Inc.,* 756 F.2d 1556, 1564 (Fed.Cir.1985).

B. *The Doctrine of Equivalents*

*22 32. A claim is infringed under the doctrine of equivalents if the accused product does substantially the same work in substantially the same way to achieve substantially the same result as the patented invention. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.,* 339 U.S. 605 (1950). The Supreme Court has described the doctrine of equivalents thus:

But courts have also recognized that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing.... Outright and forthright duplication is a dull and very rare type of infringement. To prohibit no other would place the inventor at the mercy of verbalism and would be subordinating substance to form. It would deprive him of the benefit of his invention and would foster concealment rather than disclosure of inventions, which is one of the primary purposes of the patent

system. The doctrine of equivalents evolved in response to this experience.

.. The theory on which it is founded is that "if two devices do the same work in substantially the same way, and accomplish substantially the same result they are the same, even though they differ in name, form or shape." [citing cases]. The doctrine operates not only in favor of the patentee of a pioneer or primary invention, but also for the patentee of a secondary invention consisting of a combination of old ingredients which produce new and useful results, [citing cases], although the area of equivalence may vary under the circumstances. 339 U.S. at 607-08 (footnote omitted).

33. The doctrine of equivalents prevents an infringer from stealing the fruits of anothers' invention by taking the gist of his invention while narrowly skirting the words of the claim. *Laitram Corp. v. Cambridge Wire Cloth Co.*, 863 F.2d 855, 857 (Fed.Cir.1988), *cert. denied,* 109 S.Ct. 2069 (1989).

[T]he doctrine, in a proper case, 'temper[s] unsparing logic and prevent[s] an infringer from stealing the benefits of an invention.' In that sense, the doctrine recognizes a fact of the real business world: words are not misappropriated; claimed inventions are. *Id.* (citations omitted).

34. After careful review of all evidence and testimony presented in this case, the court is compelled to conclude that defendants have successfully demonstrated by a preponderance of the evidence that the plaintiff has infringed defendants' patent.

C. *35 U.S.C. § 271(e)(1)*

35. Injunctive relief against a patent infringer is the norm. *KSM Fastening System, Inc. v. H.A. Jones Co.*, 776 F.2d 1522, 1524 (Fed.Cir.1985). Without the right to obtain an injunction, a patentee's right to exclude others would be worth only a fraction of its intended value, which would sharply diminish the incentive to create and innovate intended by the patent statute. *Smith Int'l., Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1577-8 (Fed.Cir.1983), *cert. denied,* 464 U.S. 996 (1989).

***23** 36. Uses of a patented invention not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs" is an act of infringement. 35 U.S.C. § 271(e)(1). The statute does not permit other uses, such as obtaining foreign premarketing approval and any promotional or commercial use in the U.S. or abroad. The intent of this statute was narrowly limited by Congress to permitting generic manufacturers to establish the bioequivalency of a generic substitute drug. *Scripp's Clinic & Research Foundation v. Genentech,* 666 F.Supp. 1379, 1396 (N.D.Cal.1987); *American Standard, Inc. v. Pfizer Inc.*, 722 F.Supp. 86, 103 (D.Del.1989).

37. The scope of the injunction should be sufficiently broad to prohibit all activities relating to the use of norgestimate by Ortho and J & J except those activities solely for uses reasonably related to obtaining FDA approval, as provided by 35 U.S.C. § 271(e)(1). *Eli Lilly and Co. v. Medtronic Inc.*, 14 U.S.P.Q.2d 1352 (E.D.Pa.1990), *aff'd. on other grounds,* 1990 U.S. Lexis 3184 (U.S. Jun 18, 1990) (LEXIS, GenFed library, Dist File).

D. *No Willful Infringement*

38. 35 U.S.C. § 285 permits a court in exceptional cases to award attorney's fees to the prevailing party in a patent dispute.

39. A finding of willfulness requires a consideration of the "totality of the circumstances," including whether or not the alleged infringer exercised due care to determine whether there is infringement. *Spindelfabrik Suessen-Schurr v. Schubert & Salzer,* 829 F.2d 1075, 1084 (Fed.Cir.1987), *cert. denied,* 484 U.S. 1063 (1988). *Underwater Devices Inc. v. Morrison Knudsen Co.*, 717 F.2d 1380, 1381-90 (Fed.Cir.1983) ("where ... a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing ... [the opinion of counsel here was inadequate for reasons which included an inadequate infringement analysis]").

40. In order to prove willful infringement, a showing by clear and convincing evidence under all the facts and circumstances must be present to determine willful disregard of the patent in suit. *Underwater Devices, Inc. v. Morrison-Knudsen Co.*, 717 F.2d 1380, 1389-90 (Fed.Cir.) *cert. dismissed,* 474 U.S. 976 (1985).

41. There is no willful infringement when the accused infringer reasonably relied upon an opinion of counsel-even if that opinion is ultimately proved wrong after trial. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1579 (Fed.Cir.1986), *modified,* 231 U.S.P.Q. 160 (Fed.Cir.1986) *cert. denied* 479 U.S. 1034 (1987).

42. The court concludes that Ortho obtained and reasonably relied upon opinions rendered by counsel. There was no willful infringement.

E. *Johnson & Johnson has Infringed the '322 Patent*

43. Section 271(a) of the Patent Statute states, in pertinent part: "[W]hoever without authority makes, uses, or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a).

***24** 44. Section 271(b) states: "Whoever actively induces infringement shall be liable as an infringer." 35 U.S.C. § 271(b).

45. The court further concludes that whereas Ortho and J & J's PRI used norgestimate during the term of the '322 patent, both are infringing the '322 patent and have induced infringement.

An appropriate Order follows.

ORDER

AND NOW, this 17th day of August, 1990, following the conclusion of a bench trial in this matter, and in accordance with the foregoing Findings of Fact and Conclusions of Law, it is hereby Ordered as follows:

1. Plaintiff Ortho Pharmaceutical Corporation, and Johnson & Johnson, are ENJOINED from making, using or selling any product containing the chemical compound norgestimate in violation of defendant American Home Product's '322 Patent UNTIL the expiration of the defendant's '322 Patent in November of 1991. The single exception to this is that Ortho Pharmaceutical and Johnson & Johnson MAY engage in activities with respect to norgestimate RELATED SOLELY for uses reasonably related to obtaining FDA approval, as provided by 35 U.S.C. § 271(e)(1).

2. Plaintiff's and Defendants' cross-motions for attorney's fees are DENIED.

Judgment is hereby ENTERED in FAVOR of Defendants Herchel Smith, American Home Products Corporation, and Wyeth-Ayerst Laboratories and AGAINST Plaintiff Ortho Pharmaceutical Corporation.

AND IT IS SO ORDERED.

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